K120697



APR - 5 2012

# 510 (K) Summary

**Date Prepared:** February 29, 2012

**Submitted by:** Volcano Corporation
3661 Valley Centre Dr.
Suite 200
San Diego, CA 92130

**Contact person:** Marilyn Pourazar
Senior Director of Regulatory Affairs

**Phone number:** (858) 720-4116

**Facsimile number:** (858) 720-0612

**Device Name:** Eagle Eye Platinum ST Catheter

| **Classification Name:** | **Class** | **Product Code** |
|---|---|---|
| 21 CFR 870.1200 Diagnostic Intravascular Catheter | II | OBJ |
| 21 CFR 892.1570 Diagnostic Ultrasound Transducer | II | ITX |

**Predicate Device:** Eagle Eye Platinum Digital IVUS Catheter

The Volcano **Eagle Eye Platinum ST Catheter** is substantially equivalent to the following:

| 510(k) Number | Product Name | Clearance Date |
|---|---|---|
| K092596 | Eagle Eye Platinum Digital IVUS Catheter | December 10, 2009 |

**Device Description:**

The **Eagle Eye Platinum ST Catheter** incorporates a cylindrical ultrasound transducer array. The array radiates acoustic energy into the surrounding tissue and detects the subsequent echoes. The information from the echoes is used to generate real-time images of the coronary and peripheral vessels.

The **Eagle Eye Platinum ST Catheter** utilizes an internal lumen that allows the catheter to track over the 0.014" (0.36 mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip. The catheter is introduced percutaneously or via surgical cutdown into the vascular system.
Three 1 mm-long radiopaque markers are incorporated on the internal lumen positioned 10 mm apart from distal edge to distal edge, starting 10 mm from the proximal edge of the portion of the scanner marker tube normally visible under fluoroscopy.

**The Eagle Eye Platinum ST Catheter** may only be used with the In-Vision Imaging System, Volcano s5 or Volcano s5i Imaging System. These systems use Volcano VH IVUS system software v1.2 or higher. This catheter will not operate if connected to any other imaging system.

**Intended Use:**

The **Eagle Eye Platinum ST Catheter** is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

**Device Technological Characteristics and Comparison to Predicate Device:**

The Volcano Corporation **Eagle Eye Platinum ST Catheter** is substantially equivalent to the predicate device, **Eagle Eye Platinum Digital IVUS Catheter**.

The **Eagle Eye Platinum ST catheter** uses the same fundamental scientific technology and has the same intended use as that of the predicate device.

**Performance Data:**

Applicable testing was performed in accordance with the Design Verification Plan including a Risk Analysis addressing the impact of enhancements to the device and components. The test results indicate the **Eagle Eye Platinum ST Catheter** is comparable to the predicate device.

K120697



**Conclusion:**

The Volcano **Eagle Eye Platinum ST Catheter** has the same performance specifications, fundamental scientific technology and intended use as that of the predicate device, **Eagle Eye Platinum Digital IVUS Catheter**. The design enhancements to the device do not raise any new questions regarding safety or efficacy. The performance data and a declaration of conformity with design controls support a determination of continuing substantial equivalence of the modified device to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Volcano Corporation
c/o Ms. Marilyn Pourazar
Senior Director, Regulatory Affairs
3661 Valley Centre Dr. Suite 200
San Diego, CA 92130

APR - 5 2012

Re: K120697
Trade/Device Name: Eagle Eye Platinum Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: OBJ, ITX
Dated: March 5, 2012
Received: March 7, 2012

Dear Ms. Pourazar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120697



510(k) Number (if known): K120697

**Device Name:** **Eagle Eye Platinum ST Catheter**

**Indications for Use:**

The **Eagle Eye® Platinum ST catheters** are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

The **Eagle Eye Platinum ST** ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120697